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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,912	03/08/2004	James M. Brugger	T4342-14198US23	1670

21890 7590 03/18/2008

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EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
03/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,912	BRUGGER ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 16-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,16-25,28 and 29* is/are rejected.

7)☒ Claim(s) *26,27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-12, 16-27 have been considered but are moot in view of the new ground(s) of rejection.

2. As to applicant's assertion that the previous action examined an incorrect set of claims, this action addresses all claims pending and, since applicant has also amended the independent claims 1, 9 and 20 after the non-final action was mailed, this action is final.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-12, 16-18, 20-23 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Robinson et al (U.S. Patent No. 6,817,984).

With respect to **claim 1:** Robinson teaches a blood processing system, comprising a blood treatment device 2 with at least one peristaltic pump mechanism in the collective form of roller assemblies 46 and 72 and pinch valve V1 that capture tubing portions 44,76,94 respectively, between the instant roller assemblies 46,72, and pinch valve V1 and roller tracks 100,102,104

to cause peristaltic pumping of the fluid passing through said tubes 44,76,94. The system of Robinson comprises a cartridge in the form of cassette 26 with a fluid circuit supported thereby that is fixed within U-shaped openings in cassette 26. The fluid circuit has respective portions, the tubing portions 44,76,94, to engage said at least one peristaltic pump mechanism, i.e roller assemblies 46,72 or pinch valve V1 and respective roller tracks 100,102,104 collectively. The blood treatment device 2 includes separate engagement elements in the form of door 34 carrying the cassette 26 having the fluid circuit respective portions therein and panel 14 which are movable relative to each other in a pivoting motion via support rod 32 and mounting block 36 to be brought together around said fluid circuit respective portions 44,76,94 to engage said fluid circuit portions by forcing a first of said engagement elements (door 34) against a second of said engagement elements (panel 14). Since the peristaltic pump mechanism comprises the roller assemblies 46,54 and 72, located on the panel 14, and the roller tracks 100,102,104 are located on the door 34, both of the engagement elements 14 and 34 carry the peristaltic pump mechanism, thus meeting the limitation “at least one of the engagement elements carrying the peristaltic pump mechanism”. The blood treatment device 2 has a support in the form of cassette holder 24 configured to permit the cartridge 26 to rest
thereon and an alignment member in the form of a latch latching door 34 to housing 4. The support 24 is shaped to align the cartridge 26 (via placement of cartridge 26 in holder 24 via rails 28) with the at least one peristaltic pump mechanism, i.e. the roller assemblies 46,54,72, when the cartridge 26 is moved horizontally toward the alignment member. The support and alignment member of Robinson are such that a single vertical motion of the cartridge 26 along rails 28 to rest the cartridge on the support 24, followed by a single horizontal motion of the door 34 with cartridge 26 rested thereon to engage the alignment member, i.e. the latch, positions the cartridge 26 such that the separate engagement elements, the door 34 and panel 14 on housing

4, are brought together around the respective fluid circuit portions 44,76,94 to engage the at least one peristaltic pump mechanism, namely the roller assemblies 46,54,72 disposed on panel 14. As to the limitation “renal replacement therapy system”, the device of Robinson anticipates all of the limitations of claim 1 and thus is also functional as a renal replacement therapy system.

With respect to **claim 2:** The fluid circuit disposed on cartridge 26 includes an extracorporeal blood circuit.

With respect to **claim 3:** The fluid circuit is configured for circulating blood from an individual through the blood treatment device 2 to remove waste and to return blood and replacement fluid to the individual after removal of waste. The respective portions 44,76,94 include a first portion 76 for conveying waste, i.e. separated plasma, a second portion 44 for conveying blood, and a third portion 94 for conveying replacement fluid from tubing 94 connected to bag 92 containing Nutricel, an additive considered herein to be a replacement fluid as the term “replacement fluid” is disclosed.

With respect to **claim 4:** The at least one actuator includes a peristaltic pump with a single rotating element in the form of a roller assembly 46/54/72 that pumps blood through multiple ones of said respective portions 44,76,94. The respective portions carry different fluids including at least blood (portion 44) and another fluid (portion 94).

With respect to **claim 5:** The “at least another fluid” taught by Robinson includes replacement fluid in the form of Nutricel ® replacement fluid (portion 94).

With respect to **claim 6:** The "at least another fluid" is carried by respective portion 76 and includes waste
fluid in the form of separated plasma.

With respect to **claim 7:** The first of said engagement elements, door 34, includes said fluid circuit which itself includes filter 70. Thus said first engagement element 34 taught by Robinson includes a filter.

With respect to **claim 8:** The first of said engagement elements 34 is permanently attached to said fluid circuit via adhesive fixing the fluid circuit portions to openings in said cassette 26. Since the device of Robinson meets all of the limitations of claim, the limitation "forming a sterile consumable component which is replaced after a fixed number of treatments" flows inherently and necessarily from the teachings of Robinson.

With respect to **claim 9:** Robinson teaches a method of blood processing using a blood treatment device with at least one peristaltic pump mechanism in the collective form of roller assemblies 46,54,72, respective pinch valves V1-*Vn* and mating roller tracks 100,102,104. The at least one peristaltic pump mechanism is carried by at least one of two separate engagement elements inasmuch as the second engagement element, panel 14, carries the roller assemblies 46,54,72 and pinch valves V1-V*n*. A fluid circuit with respective portions in the form of tubing lines 44, 76 and 94 engage said at least one peristaltic pump mechanism. Specifically, portion 44 engages roller assembly 46, portion 76 engages pinch valve V3, and portion 94 engages pinch valve V1. The method of Robinson comprises the steps of: locating said fluid circuit

respective portions 44,76,94 between said separate engagement elements inasmuch as the tubing portions 44,76,94 are located on the surface of cartridge 26, the first engagement element, and the tubing portions face panel 14, a second engagement element. The fluid portions are located between engagement elements by inserting cartridge 26 upon which the fluid circuit respective portions lie into cartridge support 24. As can be seen in Figs. 2 and 3, cartridge support 24 is located between door 34 and panel 14 and thus when the cartridge is placed in the support 24, the fluid respective portions lying thereon are now between separate engagement elements, the cartridge 24 and the panel 14. The method also comprises moving at least one of said engagement elements, door 34, toward the other, panel 14, to bring them together such that the engagement elements squeeze said respective portions therebetween. The method comprises the step of operating a pump, specifically the peristaltic pump mechanism when the device is powered on, in one of said engagement portions, panel 14, to convey at least blood and at least one other fluid, i.e. Nutricel ® red cell storage solution in order to perform a therapeutic treatment. With respect to the limitation “a method of performing renal replacement therapy using a blood treatment device”, the method of blood processing taught by Robinson using a blood treatment device 2 teaches all of the claimed method steps, therefore the method of Robinson inherently and necessarily is functional as a method of performing renal replacement therapy as well.

With respect to **claim 10:** The respective portions include fluid lines 44,76,94, and said step of locating includes laying said fluid lines on a peristaltic pump. Specifically, when the engagement elements are brought together, fluid lines 44,76,94 are physically positioned between roller tracks 100/102/104 and roller assemblies 46/54/72 over pinch valves V1-V*n*, all of which constitute the peristaltic pump.

With respect to **claim 11:** The method of Robinson further comprises disposing of said first of said engagement elements, cartridge 26, and replacing it with another after a fixed number of treatments.

With respect to **claim 12:** Robinson teaches that the cartridge 26 is “typically disposed of” after “it is determined that blood is no longer needed from the donor" and discloses the step of disposing as a step of one iteration of the entire blood treatment process. These teachings are interpreted herein as a disclosure by Robinson that the cartridge 26 is disposed after each iteration of the blood treatment process. Thus the fixed number of treatments after which the first engagement element, cartridge 26, is disposed of is one.

With respect to **claim 16:** The alignment member, i.e. the latch that latches door 34 to panel 14, can be seen in Fig. 19. Robinson teaches that the door 34 is latched to panel 14 but does not identify this element in Fig. 19 with a reference character. The structural element in Fig. 19 directly above the leftmost pin 470 is interpreted herein by examiner as being a latch and includes a raised portion of the blood treatment device, specifically a raised portion of panel 14 and housing 4.

With respect to **claim 17:** The support 24 taught by Robinson includes a pair of rails 28.

With respect to **claim 18:** The support 24 includes a pair of rails 28 that support a part of the blood treatment device that carries a subset of the separate engagement elements, namely the

fluid circuit, which would constitute a subset of the separate engagement elements, i.e. cartridge 26 and panel 14.

With respect to **claim 20:** Robinson teaches a blood processing system, comprising a blood treatment device 2 with at least one peristaltic pump in the collective form of roller assemblies 46 and 72 and pinch valves V1-V*n* that capture tubing portions 44,76,94 respectively, between the instant roller assemblies 46,72, and pinch valve V1 and roller tracks 100,102,104 to cause peristaltic pumping of the fluid passing through said tubes 44,76,94. The system of Robinson comprises a cartridge in the form of cassette 26 with a fluid circuit supported thereby that is fixed within U-shaped openings in cassette 26. The fluid circuit has respective portions, the tubing portions 44,76,94 engageable with said at least one peristaltic pump mechanism, i.e roller assemblies 46,72 or pinch valve V1 and respective roller tracks 100,102,104, collectively. The blood treatment device 2 includes separate engagement elements in the form of door 34 carrying the cassette 26 having the fluid circuit respective portions therein and panel 14 which are movable relative to each other in a pivoting motion via support rod 32 and mounting block 36 to be brought together around said fluid circuit respective portions 44,76,94 to engage said fluid circuit portions by forcing a first of said engagement elements (door 34) against a second of said engagement elements (panel 14). Since the peristaltic pump mechanism comprises the roller assemblies 46,54 and 72, located on the panel 14, and the roller tracks 100,102,104 are located on the door 34, both of the engagement elements 14 and 34 carry the peristaltic pump mechanism, thus meeting the limitation “at least one of the engagement elements carrying the peristaltic pump mechanism”. The blood treatment device 2 has a support in the form of cassette holder 24 configured to permit the cartridge 26 to rest thereon and an alignment member in the form of a latch latching door 34 to housing 4. The alignment member is

considered herein to be shaped to align the cartridge 26 with the at least one peristaltic pump mechanism, i.e. the roller assemblies 46,54,72, when the cartridge 26 is moved horizontally, as Robinson teaches that this alignment is achieved when door 34 is latched using said latch alignment member to panel 14. The support and alignment member of Robinson are such that a single vertical motion of the cartridge 26 along rails 28 to rest the cartridge on the support 24, followed by a single horizontal motion of the door 34 with cartridge 26 rested thereon to engage the alignment member, i.e. the latch, positions the cartridge 26 such that the separate engagement elements, the door 34 and panel 14 on housing 4, are brought together around the respective fluid circuit portions 44,76,94 to engage the at least one peristaltic pump mechanism, namely the roller assemblies 46,54,72 disposed on panel 14. As to the limitation “renal replacement therapy system”, the device of Robinson anticipates all of the limitations of claim 20 and thus is also functional as a renal replacement therapy system.

With respect to **claim 21:** The alignment member, i.e. the latch that latches door 34 to panel 14, can be seen in Fig. 19. Robinson teaches that the door 34 is latched to panel 14 but does not identify this element in Fig. 19 with a reference character. The structural element in Fig. 19 directly above the leftmost pin 470 is interpreted herein by examiner as being a latch and includes a raised portion of the blood treatment device, specifically a raised portion of panel 14 and housing 4.

With respect to **claim 22:** The support 24 taught by Robinson includes a pair of rails 28.

With respect to **claim 23:** The support 24 includes a pair of rails 28 that support a part of the blood treatment device that carries a subset of the separate engagement elements, namely the

fluid circuit, which would constitute a subset of the separate engagement elements, i.e. cartridge 26 and panel 14.

With respect to **claim 25:** The support 24 includes a horizontal member connecting the rails 28 as can be seen in Fig. 2 and is further illustrated herein.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 19 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson (‘984).

With respect to **claims 19,24:** The support 24 includes a pair of rails 28 that support a part of the blood treatment device that carries a subset of the separate engagement elements, namely a subset of cartridge 26. The part of the blood treatment device includes a door 34. Robinson

teaches a control panel 16 but teaches that it is positioned on housing 4 and thus Robinson does not teach a door with a control panel thereon. However, Robinson also teaches that the control panel 16 can be physically separated from the housing 4 and moved elsewhere, where it can be operably coupled to housing 4 by cables, which is interpreted herein as a teaching by Robinson that the control panel can be relocated from the housing 4 without any impairment of function. If the panel were moved to the door 34, the visibility and functionality of the panel would be preserved and the panel's position on the door would interfere in no way with the proper function of the control panel 16 as taught by Robinson. Therefore it would be obvious to one of ordinary skill in the art to modify the device of Robinson such that said part of the blood treatment device includes a door with a control panel thereon with a reasonable expectation of success to provide a means for the user to control the treatment process.

8. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson in view of Dennehey et al (U.S. Patent No. 5,462,416).

With respect to **claim 28:** Robinson teaches a method of blood processing using a therapy machine including at least one pump race in the form of an opening on cartridge 26 that aligns with access opening 47 of panel 14 housing the roller assemblies of the peristaltic pump. The opening on the cartridge is considered herein to be a pump race because when the door 34 is latched to the housing 4 to prepare for use, the tubing lines of the fluid circuit pass over the opening and are squeezed between roller assemblies and roller tracks 100,102,104, defining a means for engaging the tubing with the pump, hence the opening is a pump race. Robinson teaches at least one pump roller in the form of roller assemblies 46,54,72, an alignment member in the form of a latch latching door 34 and housing 4 together, and a fluid circuit with at least two

tubes 44,76,94, comprising: moving the fluid circuit horizontally toward the alignment member by pivoting door 34 having cartridge 26 attached and supported thereon toward panel 14, until the fluid circuit is engaged by the alignment member restricting the movement of the at least two tubes 44,76,94 and causing the at least two tubes to be in alignment with the at least one pump roller 46,54,72. The method of Robinson comprises the step of moving the at least one pump roller 46,54,72 and the at least one pump race in the form of the opening in the cartridge 26 aligning with access opening 47 in a direction that is considered herein to be mutually horizontal. Applicant has not defined the term “mutually horizontal” in the disclosure. The generally horizontal movement of the cartridge 26 once it is disposed within support 24 and moved toward panel 14 and the fact that the plane of the cartridge 26 and the plane of the panel 14 are parallel creates a direction of movement of the cartridge 26 toward the panel 14 that is a horizontal direction with respect to the cartridge 26 and also be a horizontal direction with respect to the panel 14. The method of Robinson teaches operating the at least one pump roller 46,54,72 to convey blood through one of the at least two tubes 44,76,94, specifically tube 44, and to convey at least one non-blood fluid, namely Nutricel ® additive, through another of the at least two tubes, tube 94. With respect to the limitation “a method of performing renal replacement therapy using a blood treatment device”, the method of blood processing taught by Robinson using a blood treatment device 2 teaches all of the claimed method steps, therefore the method of Robinson inherently and necessarily is functional as a method of performing renal replacement therapy as well.

Robinson does not teach that the pump roller is moved in this mutually horizontal direction. Dennehey teaches a blood treatment device wherein a cartridge is placed in a slot between a tray and a panel similar to panel 14 on housing 4 taught by Robinson. Since the device of Dennehey and Robinson seek to solve a similar problem in the art (provide a means

for holding a cartridge having a fluid circuit thereon in operable engagement with pumps to pump blood through a processing loop) and function in a substantially identical manner to filter and treat a volume of a patient's blood, it would be obvious to one of ordinary skill in the art to modify the method of Robinson so as to include a step of moving an instant at least one pump roller and an instant at least one pump race in mutually horizontal directions with a reasonable expectation of success to ensure that the instant cartridge with fluid circuit thereon will effectively engage the pump mechanism to begin treatment.

With respect to **claim 29:** The method of Robinson further comprises providing the fluid circuit in a cartridge 26 and resting the cartridge 26 on a support 24 prior to moving the fluid circuit horizontally toward the alignment member, i.e. the latch.

Allowable Subject Matter

9. Claims 26 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Indicating Allowable Subject Matter

10. The following is a statement of reasons for the indication of allowable subject matter: A thorough search of the prior art of record did not disclose any reference, alone or in combination with other reference(s) that teaches or fairly suggests a chassis and a door connected by rails.

Robinson teaches the claimed invention substantially as claimed except for the limitation “wherein said first and second opposing portions are connected by rails at bottom ends thereof and said support includes at least a portion of said rails.” Robinson does not teach or fairly

suggest that the chassis 4 and door 34 are connected by rails to a door, said door being movable with respect to said chassis such that when said cartridge is placed in said slot is closed around said cartridge. Robinson explicitly teaches that the door 34 rotates about a support shaft 32 toward the chassis 4, therefore it would not be obvious to one of ordinary skill in the art to modify the device of Robinson such that the chassis and door are connected by rails, as such a modification could not be accomplished with a reasonable expectation of success.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761